**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and LTS LOHMANN THERAPIE-SYSTEME AG<br><br>Plaintiffs,<br><br>v.<br><br>PAR PHARMACEUTICAL, INC.<br><br>Defendant. | C.A. No. 13-1467-RGA |

**DEFENDANT PAR PHARMACEUTICAL, INC.'S ANSWER AND COUNTERCLAIMS**

Par Pharmaceutical, Inc. ("Par"), answers the Complaint of Novartis Pharmaceuticals Corporation, Novartis AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (collectively, "Plaintiffs") as follows:

## NATURE OF ACTION

1. This is an action for patent infringement.

**Answer:** Par admits that Plaintiffs purport to bring this action for patent infringement. Par denies that Plaintiffs properly state a claim for patent infringement.

## PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

**Answer:** Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore denies them.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

**Answer:** Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and therefore denies them.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

**Answer:** Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint and therefore denies them.

5. Plaintiff Novartis International Pharmaceutical Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at 131 Front Street, Hamilton HM12, Bermuda.

**Answer:** Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint and therefore denies them.

6. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

**Answer:** Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of the Complaint and therefore denies them.

7. On information and belief, defendant Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at One Ram Ridge Road, Spring Valley, New York 10977.

**Answer:** Par admits the allegations in paragraph 7 of the Complaint.

## JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

**Answer:** Par admits that Plaintiffs purport to bring this action under the patent laws of the United States of America. Par denies that Plaintiffs properly state a claim for patent infringement. Par further states that it does not contest subject matter jurisdiction.

9. On information and belief, Par is incorporated in Delaware and has purposely availed itself of the rights and benefits of Delaware law and this Court.

**Answer:** Par admits that it is incorporated in Delaware. Par further states that it does not contest personal jurisdiction for purposes of this action.

10. On information and belief, Par is in the business of manufacturing, marketing, importing into the United States and selling pharmaceutical drug products, including generic drug products. On information and belief, Par directly or through its affiliates and agents markets and sells drug products throughout the United States and in this judicial district, and has purposely availed itself of the rights and benefits of Delaware law and this Court.

**Answer:** Par admits that it is in the business of, among other activities, manufacturing, marketing, importing into the United States and selling pharmaceutical drug products, including

generic drug products, throughout the United States, including in the State of Delaware. Par further states that it does not contest personal jurisdiction for purposes of this action.

11. This Court has personal jurisdiction over Par by virtue of, *inter alia*, the above-mentioned facts.

**Answer:** Par states that it does not contest personal jurisdiction for purposes of this action.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

**Answer:** Par states that it does not contest venue in this Court.

**CLAIM FOR RELIEF – PATENT INFRINGEMENT**

13. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the United States Food and Drug Administration ("FDA") on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/2 hr and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

**Answer:** Par states that the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists the holder of NDA No. 22-083 as "Novartis." Par further states that the Orange Book indicates that NDA No. 22-083 includes rivastigmine transdermal extended release film in 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage

strengths, having the proprietary name Exelon®, and that the film contains the active ingredient rivastigmine. Par further states that the Orange Book lists an approval date of July 6, 2007 for the 4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths, and an approval date of August 31, 2012 for the 13.3 mg/24 hr dosage strength. Par further states that the FDA-approved labeling for Exelon® Patch states that it is indicated for treatment of "mild, moderate, and severe dementia of the Alzheimer's type" and "mild to moderate dementia associated with Parkinson's disease." Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 of the Complaint and therefore denies them.

14. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

**Answer:** Par admits the allegations in paragraph 14 of the Complaint.

15. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

**Answer:** Par states that the USPTO assignment database lists Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG as the assignees of the '031 patent. Par admits that the '031 patent was issued on January 1, 2002, but denies that it was duly and legally issued. Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15 of the Complaint and therefore denies them.

16. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-Nmethylphenyl carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as

transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the '031 patent is attached hereto as Exhibit A.

**Answer:** Par admits that Exhibit A appears to be a true and correct copy of the '031 patent. Par states that the claims of the '031 patent speak for themselves. Par denies the remaining allegations in paragraph 16 of the Complaint.

17. The '031 patent was initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

**Answer:** Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 of the Complaint and therefore denies them.

18. On information and belief, Par submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal system, 13.3 mg/24 hr dosage strength ("Par's ANDA Product") before the expiration of the '031 patent.

**Answer:** Par states that it submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal extended release film, 13.3 mg/24 hr dosage strength ("Par's ANDA Product") before the expiration of the '031 patent. Par denies the remaining allegations in paragraph 18 of the Complaint.

19. On information and belief, Par made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '031 patent is invalid and/or will not be infringed.

**Answer:** Par admits the allegations in paragraph 19 of the Complaint.

20. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Par's ANDA Product before the expiration of the '031 patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2).

**Answer:** Par denies the allegations in paragraph 20 of the Complaint.

21. On information and belief, when Par filed its ANDA, it was aware of the '031 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '031 patent was an act of infringement of that patent.

**Answer:** Par admits that it was aware of the existence of the '031 patent when Par filed its ANDA. Par denies the remaining allegations in paragraph 21 of the Complaint.

22. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Product will infringe one or more claims of the '031 patent.

**Answer:** Par denies the allegations in paragraph 22 of the Complaint.

23. On information and belief, the commercial manufacture of Par's ANDA Product will involve direct infringement of the '031 patent. On information and belief, this will occur at Par's active behest, and with Par's intent, knowledge and encouragement. On information and belief, Par will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

**Answer:** Par denies the allegations in paragraph 23 of the Complaint.

24. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Par's ANDA Product be a date that is not earlier than January 8, 2019, the expiration date of

the '031 patent, and an award of damages for any commercial sale or use of Par's ANDA Product and any act committed by Par with respect to the subject matter claimed in the '031 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

**Answer:** Par denies the allegations in paragraph 24 of the Complaint.

25. On information and belief, Par has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Product, including seeking approval of that product under Par's ANDA.

**Answer:** Par admits that it is currently seeking approval of Par's ANDA Product under Par's ANDA. Par denies the remaining allegations in paragraph 25 of the Complaint.

26. There is a substantial and immediate controversy between Plaintiffs and Par concerning the '031 patent. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Par will infringe and/or induce infringement of one or more claims of the '031 patent.

**Answer:** Par admits that there is a controversy between Plaintiffs and Par concerning the '031 patent. Par denies the remaining allegations in paragraph 26 of the Complaint, and specifically denies that Par will infringe and/or induce infringement of one or more claims of the '031 patent.

## PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to any of the relief they seek in their Complaint.

## AFFIRMATIVE DEFENSES

1. The claims of the '031 patent are invalid under 35 U.S.C. § 1 *et seq.* (including, *inter alia*, 35 U.S.C. §§ 102, 103 and/or 112) and/or the doctrine of obviousness-type double patenting.

2. Par's filing of an ANDA on rivastigmine transdermal extended release film, 13.3 mg/24 hr dosage strength, was not an act of infringement of any claim of the '031 patent.

3. The manufacture, use, offer for sale, sale, marketing, distribution, or importation of the product that is the subject of Par's ANDA on rivastigmine transdermal extended release film, 13.3 mg/24 hr dosage strength, would not infringe any claim of the '031 patent.

4. The Complaint fails to state a claim for which relief can be granted.

5. The relief requested in the Complaint is barred by the doctrines of estoppel and/or waiver.

## COUNTERCLAIMS

Par Pharmaceutical, Inc. ("Par") asserts the following counterclaims against Novartis Pharmaceuticals Corporation, Novartis AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (collectively, "Counterclaim Defendants")

## PARTIES

1. Counterclaim Plaintiff Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. Counterclaim Defendant Novartis Pharmaceuticals Corporation asserts in its Complaint that it is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Counterclaim Defendant Novartis AG asserts in its Complaint that it is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Counterclaim Defendant Novartis Pharma AG asserts in its Complaint that it is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Counterclaim Defendant Novartis International Pharmaceutical Ltd. asserts in its Complaint that it is a corporation organized and existing under the laws of Bermuda, having an office and place of business at 131 Front Street, Hamilton HM12, Bermuda.

6. Counterclaim Defendant LTS Lohmann Therapie-Systeme AG asserts in its Complaint that it is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

**NATURE OF THE ACTION**

7. Par seeks declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent No. 6,335,031 is invalid and not infringed by Par.

**JURISDICTION**

8. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Counterclaim Defendants based, *inter alia*, on the filing by Counterclaim Defendants of this lawsuit in this jurisdiction.

**VENUE**

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d), 1400(b), and Counterclaim Defendants' choice of forum.

## BACKGROUND

9. U.S. Patent No. 6,335,031 ("'031 patent") entitled "TTS containing an antioxidant," issued on January 1, 2002.

10. On information and belief, Novartis AG and LTS Lohmann Therapie-Systeme AG are the assignees of the '031 patent.

11. On information and belief, Novartis Pharmaceuticals Corporation is the holder of New Drug Application No. 022519 ("NDA 022083") for rivastigmine transdermal extended release film, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr, marketed under the brand name Exelon® Patch. In connection with NDA 022083, Novartis Pharmaceuticals Corporation caused the U.S. Food and Drug Administration ("FDA") to list the '031 patent in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

12. Par submitted to the FDA an Abbreviated New Drug Application ("ANDA") requesting regulatory approval to engage in the commercial manufacture, use, or sale of rivastigmine transdermal extended release film, 13.3 mg/24 hr ("Par's Rivastigmine Product") before the expiration of the Orange Book patents listed for Exelon® Patch. Par made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the '031 patent listed in the Orange Book for Exelon® Patch is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par's Rivastigmine Product.

## COUNT ONE

### (Declaratory Judgment regarding invalidity of U.S. Patent No. 6,335,031)

13. Par realleges paragraphs 1-12 of the Counterclaims as if fully set forth herein.

14. The claims of the '031 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

15. An actual and justiciable controversy exists between the parties with respect to the '031 patent, and Par is entitled to a declaratory judgment that the '031 patent is invalid.

**COUNT TWO**

**(Declaratory Judgment regarding non-infringement of U.S. Patent No. 6,335,031)**

16. Par realleges paragraphs 1-12 of the Counterclaims as if fully set forth herein.

17. The filing of Par's ANDA on Par's Rivastigmine Product did not infringe any valid claim of the '031 patent.

18. The commercial manufacture, use, offer for sale, sale, or importation of Par's Rivastigmine Product would not infringe any valid claim of the '031 patent.

19. An actual and justiciable controversy exists between the parties with respect to the '031 patent, and Par is entitled to a declaratory judgment that the '031 patent is not infringed by Par.

**PRAYER FOR RELIEF**

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Plaintiffs and grant the following relief:

A. Declare that the claims of the '031 patent are invalid;

B. Declare that the filing of Par's ANDA on Par's Rivastigmine Product did not infringe any claim of the '031 patent;

C. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par's Rivastigmine Product would not infringe any claim of the '031 patent;

D. Award Par its costs and reasonable attorney fees to the extent permitted by law; and

E. Award Par such other and further relief as the Court deems just and proper.

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Dated: November 18, 2013

*/s/ Steven J. Fineman*

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